

REMARKS

Claim 89, now claim 161, is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons noted in the official action. The rejected claim is now rewritten by the noted new claim, and the presently pending claims are now believed to particularly point out and distinctly claim the subject matter regarded as the invention, thereby overcoming all of the raised § 112, second paragraph, rejections.

Claims 47, 48, 51, 52, 57-60, 62, 63, 65-70, 72, 74, 76, 78, 79, 84, 88, 89 and 93-99, 100 are rejected, under 35 U.S.C. § 102, as being anticipated in view of at least one of Evans et al. '490, Joseph et al. '297, Hattes '899 and Bennett et al. '472. The Applicant acknowledges and respectfully traverses the raised anticipatory rejections in view of the above new claims 101-166 and the following remarks.

In regards to Hattes '899, claim 100 has been cancelled, therefore the Examiner's objection to this claim is believed overcome. Turning to the Examiner's novelty and obviousness objections, we have rewritten independent claims 47, 62, 96 and 98 as new claims 101, 119, 139 and 149 which we believe address the Examiner's objections. We have also added further new dependent claims 102-106, 120-124, 140-148 and 150-157 respectively and deleted previous claims 48, 49, 63, 64 and 81. Some minor amendments have also been made to the subject matter of previous claims 57, 58, 72, 73 and 76 (now claims 114, 115, 132, 133 and 136).

We thank the Examiner for his thorough examination. From the Examiner's objections, it is apparent that a critical feature of the invention has not previously been clearly demonstrated in the claims. This critical feature is monitoring of motion, namely the present invention is concerned with monitoring bodily motion, by which we mean physical motion of the body and not "internal" motion such as e.g. heart rate, oesophageal pressure, etc. In order to clarify and clearly limit the claims, we have therefore rewritten each of independent claims to make clear that we are detecting "bodily motion" which is "motion of the head, limbs and trunk of the patient". For example as set forth in claim 101 "...providing a sensor arrangement which is arranged to detect motion of the head, limbs and trunk of the patient, and respiratory motion of the patient ..." This is actual physical motion of the patient i.e. moving their body trunk or their legs or arms or head. We believe that it is quite clear from the specification that it is this type of bodily motion that the invention is concerned with (see for example page 2, lines 8-11 of the original specification and throughout the specification).

It is this type of motion in particular which can change when a non-human animal patient or a human patient is awaking from, for example, medication. Further, it is this type of bodily motion which can be monitored to determine whether or not a patient is showing signs of painfulness. For example, rhythmic motion of a limb can often indicate that a non-human animal patient is in pain.

Further, for monitoring for patient arousal, the present applicants have found that it is extremely useful to monitor both bodily motion and respiratory motion. Claims 47 and 62 (now claims 101 and 119) are limited accordingly. The respiratory and bodily motion can be monitored separately or by the same sensor arrangement (dependent claims 102, 103, 104 and 105 and equivalent dependent claims to claim 119). Independent claims 101 and 119 have also been limited to the analysis being for the rate of motion.

A good illustration of an example embodiment of the present invention operating to detect for patient arousal is given by Figure 4 of the application and associated description on page 13, lines 9-28. In this embodiment, the signals from respiratory motion and head, trunk and limb movement are combined as a single signal and any increase in rate over the threshold provides an indication that the patient is becoming aroused (whether it is because of increase or commencement of bodily motion or an increase in respiratory motion).

With regard to independent claims 101 and 119, it is respectfully submitted that none of the documents cited by the Examiner show a method and device for monitoring a patient which monitors head, limb and trunk motion (bodily motion) and respiratory motion, and analyses a motion signal produced from this motion to determine patient arousal.

We believe that this method of monitoring for arousal has significant advantages, as are discussed in the specification and have been discussed in previous responses to the Examiner. In particular, the arrangement can be used to monitor for arousal in non-human animal patients, such as in a veterinary surgery. Note that we believe there is no disclosure whatsoever in the citations of the monitoring of non-human animal patients and features such as monitoring a plurality of animals in cages by having a separate monitoring apparatus for each cage and thus are not anticipated nor obvious in view of the citations.

The invention has similar advantages with a infant who is unable to communicate or an unconscious human patient who is unable to communicate.

With regard to independent claims 96 and 98, these have now been limited to the monitoring of limb, trunk and head motion to produce a motion signal, and analysing that motion signal to determine whether or not the patient is painful. It is respectfully submitted that the requirement for the analysis to determine for painfulness is an adequate limitation.

The Examiner is referred to Figures 5a and 5b and also the associated description of those figures, page 18, lines 10 -25. To analyse for pain, the device and method must include features which enable it to determine whether the motion is painful, such as the method disclosed in Figures 5a and 5b, for example. Although we appreciate the points raised in paragraph 15 of the Examiner's objections, therefore, it is respectfully submitted that claims 96 and 98 (and also amended claims 47 and 62) now traverse that objection.

Claims 96, 98 have the same advantages as discussed above, that non-human animals can be monitored for painfulness, and also humans who are unable to communicate.

With regard to the prior art cited by the Examiner:

Evans et al (US 4,502,490) discloses a device which utilises an oesophageal balloon to monitor changes in pressure and motion of the oesophagus. It does not disclose a device and method for measuring motion of the head, trunk and limbs and respiratory motion.

Joseph et al (US 5,410,297) as discussed in previous responses does not monitor for arousal or painfulness. In any event, it does not monitor head, limb, trunk motion and respiratory motion for signs of arousal. Nor does it monitor head, neck, trunk motion and analyse the motion for painfulness.

Claims 47, 48, 50-60, 62, 63, 65-70, 72, 74, 88 and 93-95 are rejected, under 35 U.S.C. § 103(a), as being unpatentable over Bennett et al. '472 in view of Hickie '965. The Applicant acknowledges and respectfully traverses the raised obviousness rejection in view of the following remarks.

As the Examiner is aware, in order to properly support an obviousness objection in view of the combination of references, the references must provide some disclosure, teaching or suggestion that they be combined in a manner to achieve the presently claimed invention.

A review of Hickie '965 discloses specifically a health monitoring device coupled to a patient for generating a signal reflecting at least one physiological condition of the patient. Turning to columns 9 and 10 of Hickie '965, the Applicant notes that specific patient interface devices 55 can include one or more patient health monitors that monitors a patient's physiological conditions, a pulse oximeter, capnometer (not shown), non-invasive blood pressure monitors; EKG, EEG, acoustical monitors (not shown). Importantly, none of these patient interface devices disclose or utilize bodily motion of any sort for example, the complete movement of the head, neck and trunk motion of the patient's body.

While it is also noted in column 10, lines 43-47 of Hickle '965 that "patient health monitors 12a generate electronic feedback signals representing actual patient physiological data which are converted to electronic signals and then provided to controller 14." The electronic feedback signals disclosed in Hickle '965 are, however, significantly different from Bennett et al. '472.

Bennett et al. '472 discloses a electrode assembly for monitoring differential electrical states in various parts of a living animal. As noted in column 5 of the '472 patent "...the electrode assembly can be used for simultaneously monitoring the nerve signals, the facial muscle groups to reflect the patients facial muscle components..." Bennett measures the nerve impulses, i.e. electrical signals, sent to target muscles groups in the body and are received by the electrode assembly 10 which is placed on the patients face in this case and thus the electrode of this device does not directly measure any motion by actually measuring electric signals and nerve impulses in the target muscle groups. This method and apparatus thus indirectly measures the activity of the muscle reflexes on the muscle face.

The Applicant has made a thorough study of Bennett et al '472 but can find no disclosure, suggestion or teaching within this reference that would cause it to be combined with the rather conventional internal physiological measurement devices of Hickle '965. Hickle '965 in fact discloses only the well known and more conventional physiological interface devices and does not suggest, in fact, that any other devices would be necessary.

Bennett et al '472 is fundamentally different, being drawn to indicating the depth of the state of unconsciousness or the awareness of the patient of the ongoing procedure. Such a device and method is not a replacement for such internal physiological monitoring and thus the Applicant asserts that there would be no reason to combine these references of Hickle et al. with the Bennett et al. 472 reference. Therefore, the Applicant does not believe that these references can be combined as suggested by the Examiner.

Even if the references can be combined, the Applicant adamantly refutes such an allegation, a combination would merely place the electrode assembly of Bennett et al. '472 with the apparatus of Hickle '965. Whereas such a combination, if possible, might provide an electrical data a monitoring of the electrical data output of a patients facial nerves and indirectly the movement of the facial muscles, there is nothing in this combination which would disclose, teach or suggest the specific step of monitoring head, limb and trunk motion and respiratory motion as specifically claimed by the Applicant. For example, head motion is not necessarily caused by any of the facial muscles and therefore even if such a

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combination of the references were possible, it would still not disclose the presently claimed feature of the present invention.

In any event, the Applicant believes the above amended paragraphs to overcome the references either alone or in combination and thus the Applicant believes these claims, as noted above, to be allowable over the combination of Bennett et al. '472 and Hickie '965 as well as any other references combined with the above discussed references.

In view of the foregoing, it is respectfully submitted that this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,



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